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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-----------------------------------|----------------------|--------------------------|------------------|--|
| 10/585,693 | 11/09/2006 | Takashi Yamashita | Q95455 | 4348 | |
| 23373 7590 11/28/2007 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. | | | EXAM | EXAMINER | |
| | | | SAJJADI, FEREYDOUN GHOTB | | |
| | SUITE 800 WASHINGTON, DC 20037 | | ART UNIT | PAPER NUMBER | |
| | | | 1633 | | |
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| | , | | 11/28/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) |
|---|---|---|
| | 10/585,693 | YAMASHITA ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Fereydoun G. Sajjadi | 1633 |
| The MAILING DATE of this communication a Period for Reply | appears on the cover sheet w | ith the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REI WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perion for reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the material patent term adjustment. See 37 CFR 1.704(b). | B DATE OF THIS COMMUNION (1.1.136(a)). In no event, however, may a relied will apply and will expire SIX (6) MON tute, cause the application to become AB | CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). |
| Status | | |
| 1) ⊠ Responsive to communication(s) filed on 10 2a) □ This action is FINAL. 2b) ⊠ T 3) □ Since this application is in condition for allow closed in accordance with the practice under | his action is non-final. wance except for formal matt | , , |
| Disposition of Claims | | |
| 4) Claim(s) 1-30 is/are pending in the application 4a) Of the above claim(s) is/are without 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-30 are subject to restriction and/ | drawn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to t Replacement drawing sheet(s) including the corr 11) The oath or declaration is objected to by the | accepted or b) objected to the drawing(s) be held in abeyar rection is required if the drawing | nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the p application from the International Burn * See the attached detailed Office action for a light | ents have been received. ents have been received in A priority documents have been eau (PCT Rule 17.2(a)). | Application No received in this National Stage |
| Attachment(s) | _ | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | Paper No(| Summary (PTO-413) s)/Mail Date nformal Patent Application |

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DETAILED ACTION

Claims 1-30 are pending in the application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 24-27, drawn to a transgenic bird obtained by microinjecting a replication-deficient retroviral vector coding for a desired protein, into the early embryo of a fertilized avian egg; and an egg laid by said transgenic bird.

Group II, claim(s) 7-14, 16-23 and 28-30, drawn to a method for constructing a transgenic bird comprising, microinjecting a replication-deficient retroviral vector coding for a desired protein, into the early embryo of a fertilized avian egg; and a method of determining the reproductive lineage of said transgenic bird.

Group III, claim(s) 15, drawn to a method for producing a protein comprising extracting a desired protein from somatic cells, blood or eggs of a transgenic bird.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-III, is a transgenic bird obtained by microinjecting a replication-deficient retroviral vector coding for a desired protein, into the early embryo of a fertilized avian egg.

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Groups I-III do not share a special technical feature over the art because the inventions lack an inventive step under PCT Article 33(3) as being obvious over Sang et al. (U.S. Patent Application Publication 2005/0273872; effective filing date: Nov. 27, 2002). Sang et al. teach the generation of a transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Experiment 1 describes the introduction of VSV-G peudotyped lentiviral vector into the subgerminal cavity below the embryo (paragraph [0064], p. 5).

The claims in Groups I-III are drawn to distinct products, and methods that utilize distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I-III, a specifically named single species of bird. The birds generically encompassed by base claim 1 include many diverse species, that include chicken, quail, turkey, ducks, ostriches, pet birds etc. (as recited on p. 5 of the specification). As such, each species is genetically, and physiologically distinct.

For Group III, a specifically named single species for the source of protein; either somatic cells, blood or eggs, as recited in claim 15.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

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the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 7, 14-17 and 24-30, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: 1-30.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features (different species of birds and different sources of protein) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.

Examiner, A.U. 1633

/Anne Marie S. Wehbé/

Primary Examiner, A.U. 1633